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April 23, 2021

Via ECF

Special Master the Hon. Thomas Vanaskie
Stevens & Lee
1500 Market Street, East Tower, 18th Floor
Philadelphia, PA 19103

Re: *In re Valsartan, Losartan, and Irbesartan Products Liability Litigation*, No.
1:19-md-2875-RBK-KMW (D.N.J.)

Dear Special Master Vanaskie:

I write on behalf of the Pharmacy Defendants to provide their position regarding which of Plaintiffs' newest round of Document Requests ("RFPs") can be negotiated now, and which should be tabled for the time being. Plaintiffs have refused to agree to table any of the nine (9) RFPs, while the Pharmacy Defendants have offered to negotiate six,¹ leaving three in dispute.

I. BACKGROUND

A. The Pharmacy Defendants Have Already Produced Documents in Response to Plaintiffs' Original RFPs

The at-issue RFPs are not Plaintiffs' first set of document requests to the Pharmacy Defendants. The Pharmacy Defendants have already issued written responses and produced

¹ The Pharmacy Defendants' offer to negotiate these six RFPs does not mean that they agree to produce documents in response to the requests, but rather that the negotiation of those requests (including the Pharmacy Defendants' objections) can occur while the pleadings are in flux.

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documents responsive to Plaintiffs' original document requests ("Original RFPs"). The Original RFPs were a set of twenty-one requests that covered sourcing; sales; warranties (upstream); warranties (downstream); testing/inspection; distribution centers; recalls; the Drug Supply Chain Security Act; document preservation; and indemnity agreements. (ECF 509-1). Given the Pharmacy Defendants' more limited role in this case, the Original RFPs did not seek custodial discovery.

Judge Schneider ordered that the Pharmacy Defendants respond to the Original RFPs without objection in August 2020, and make rolling productions of documents in August, September, and October of 2020. ECF 509 (order attaching Original Requests); ECF 518 (order setting production schedule).

B. Plaintiffs Issued a New Set of RFPs, Seeking Custodial Discovery

Having made the rolling productions and not hearing from Plaintiffs that they were in any way insufficient, the Pharmacy Defendants were surprised when Plaintiffs served the new RFPs for negotiation on December 8, 2020. Ex. A (cover email attaching RFPs). Some of these requests covered the same topics as the Original Requests (in response to which the Pharmacy Defendants already produced documents), but were broader and therefore more burdensome. For example, the Original Requests sought "[d]ocuments sufficient to show" the representations and warranties provided by the Manufacturer or Wholesaler Defendants (ECF 509-1 at Request 6) (emphasis added), and the new RFPs seek "[a]ll documents relating to any representation or warranty provided by any manufacturer, wholesaler, or other seller of VCDs to you directly or indirectly." Ex. A at Request 1 (emphasis added). Plaintiffs also sought, for the first time, custodial discovery. Unlike the Manufacturer Defendants, who negotiated custodians and search terms with Plaintiffs

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in 2019, no such track had been laid for the Pharmacy Defendants, again given their more limited role in this litigation. In Plaintiffs' correspondence serving these Requests, they noted the then-pending April 1, 2021 fact discovery deadline. Ex. A.

In December 2020, counsel for the Pharmacy Defendants began to engage in meet and confer negotiations with counsel for Plaintiffs about the RFPs and expressed concern about, *inter alia*, the burden of custodial discovery, the duplicative nature of many of the requests, and whether the requests were relevant and proportional to the needs of the case.

C. Most Claims Against the Pharmacy Defendants Were Dismissed and the Schedule Extended

Shortly thereafter, Judge Kugler began issuing a series of motion to dismiss decisions (from December 18, 2020 to March 12, 2021) that dismissed most of Plaintiffs' claims against the Pharmacy Defendants. The Court dismissed in their entirety Plaintiffs' breach of express warranty, Magnuson-Moss Warranty Act, fraud, negligent misrepresentation, consumer protection sounding in fraud, and negligence claims against the Pharmacy Defendants, and dismissed additional claims for the majority of states (*e.g.*, breach of implied warranty, products liability-manufacturing defect, products liability-failure to warn, and products liability-design defect). ECF 776, 819, 839, 1020. At their request, Plaintiffs were allowed to delay filing any motion for leave to attempt to remedy the issues identified in the motion to dismiss orders until thirty (30) days after the last motion to dismiss decision, rather than filing successive motions for leave to amend in response to each Rule 12 decision from the Court. ECF 916.²

² Plaintiffs filed their motion for leave to amend on April 12, 2021 (ECF 1148), and the parties are negotiating a briefing schedule for Defendants' opposition thereto.

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In February 2021, this Court extended all deadlines by sixty days. ECF 843, 863. As part of that extension, “[f]urther discovery, if any, of . . . retailer/pharmacy defendants” is “to begin on or after June 1, 2021,” and be completed by October 4, 2021. ECF 863.

D. Further Meet and Confer Negotiations

Given the dismissal of most claims against the Pharmacy Defendants and the extension of the discovery schedule, the Pharmacy Defendants suggested that negotiations of the RFPs be tabled while the claims against them are in flux. Just as it made more sense for Plaintiffs to file one motion for leave to amend rather than successive motions in iterative fashion, the Pharmacy Defendants argued that any additional discovery should wait until the pleadings are set, especially given the extension of the discovery schedule. *See* Ex. B (Pharmacy Defendants’ February 16, 2021 Letter). This issue was raised during the March 10, 2021 conference, during which the Court instructed the parties to meet and confer as to which requests can be negotiated now and which should be tabled. *See* 3/10/21 Tr. at 68:9-24 (“We don’t have to get one complete agreed-upon set of requests before discovery can go forward at least to a limited extent. And I think—I think, respectfully, you should meet and confer, there should be a response [from Plaintiffs] to that February 16th letter, and you should be able to identify some areas on which discovery can go forward and some where you simply say, we don’t think this is going to stay in the case so we shouldn’t have to produce that discovery.”). The Court ended the discussion by directing the parties “to meet and confer to see if you can reach agreement on what is discoverable now, even though the pleadings are still in flux.” *Id.* at 69:2-4.

Plaintiffs responded to the Pharmacy Defendants’ February 16th letter on March 12, 2021. Ex. C. Plaintiffs did not attempt to distinguish between RFPs that were appropriate to negotiate

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while the pleadings were in flux and those that were not. The Pharmacy Defendants responded on March 24, 2021, pursuant to the Court's directive, offering a compromise that four RFPs could be negotiated while the pleadings are in flux, and the remaining five should be tabled. Ex. D. The issue was raised again during the April 14, 2021 conference, where it was agreed that the parties would submit letter briefs to the Court as to which RFPs should be negotiated now while the pleadings are in flux. 4/14/21 Tr. at 17:15-19:2.

With the goal of reaching agreement without the necessity of Court intervention, on April 20, 2021, the Pharmacy Defendants proposed an additional compromise of adding two further RFPs to the set that could be negotiated while the pleadings are in flux. Plaintiffs rejected this proposal, maintaining their position that all of the RFPs must be negotiated now.

II. REQUESTS THE PHARMACY DEFENDANTS HAVE OFFERED TO NEGOTIATE

As noted above, the Pharmacy Defendants have now offered to negotiate six of the nine RFPs without waiting for further clarity regarding the pleadings. Those are:

3. All agreements relating to your purchase of VCDs (e.g., purchase/supply agreements with wholesalers, etc.).
4. All agreements relating to your sale of VCDs (e.g., contracts with third-party payors, pharmacy benefit managers, etc.).
5. All documents reflecting your inventory management policies, practices and procedures pertinent to VCDs.
6. All documents relating to the stock life for VCDs maintained in your own inventories (both distribution center and store levels), including but not limited to FIFO, LIFO, JIT, turnover ratio, replenishment/re-order triggers, and any proprietary inventory management systems.
7. All documents relating to the stock life for VCDs maintained in your inventories (both distribution center and store levels), including but not limited to FIFO, LIFO, JIT, turnover ratio, replenishment/re-order triggers, and your proprietary inventory management systems.

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9. Organizational charts or other documents sufficient to show the names, titles, and responsibilities of employees or agents involved in the following functions: (i) the purchase of VCDs; (ii) the sale of VCDs; (iii) the inventory maintenance, receiving, and shipping of VCDs; (iv) the recall of VCDs.

Ex. A at Requests 3, 4, 5, 6, 7, 9.³

III. THE PHARMACY DEFENDANTS SHOULD NOT BE REQUIRED TO NEGOTIATE REQUESTS 1, 2, OR 8 NOW

Despite the Pharmacy Defendants' good faith attempt to follow the Court's instructions and reach an agreement, Plaintiffs have taken a hard line position and refused to compromise as to any of the RFPs. Therefore, there are three (3) RFPs currently in dispute that the Pharmacy Defendants should not have to negotiate now, for the reasons discussed below. The discussion focuses on the propriety of the timing of negotiations about the requests. The Pharmacy Defendants also have objections to the substance of the requests, but those are not currently at issue, and the Pharmacy Defendants expressly reserve their rights to assert those objections when and if the timing is appropriate to negotiate them.

A. RFP 1

RFP 1 requests "All documents relating to any representation or warranty provided by any manufacturer, wholesaler, or other seller of VCDs to you directly or indirectly." Ex. A at Request 1.

In negotiations, Plaintiffs argued that this RFP is appropriate now because some implied warranty claims against the Pharmacy Defendants survived dismissal, but this request seeks

³ For the sake of simplicity and clarity of the issue currently before the Court, the Pharmacy Defendants quote verbatim the Requests as drafted by Plaintiffs. For some requests, the parties have made progress towards revisions that are acceptable to both sides.

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documents related to warranties *provided to* the Pharmacy Defendants. None of Plaintiffs' claims is about warranties *provided to* the Pharmacy Defendants.

Further, to the extent Plaintiffs argue that documents relating to manufacturer/wholesaler warranties provided to the Pharmacy Defendants go to the Pharmacy Defendants' "notice" that the VCDs might have contained impurities, not only is this far-fetched, but the fault-based claims against the Pharmacy Defendants (including negligence) have been dismissed. It is axiomatic that a party need not respond to an RFP that has no relevance to a claim or defense. Fed. R. Civ. P. 26(b) (scope of discovery limited to "matter that is relevant to any party's claim or defense . . ."). Currently there is no such claim or defense to which this RFP would be relevant, and it therefore is not appropriate to negotiate at this time.

B. RFP 2

RFP 2 requests "All documents relating to any representation or warranty provided by or passed on by you to any consumer or third-party payor who paid any amount for VCDs sold by you." Ex. A at Request 2. This seeks documents regarding express representations and warranties made by the Pharmacy Defendants to individual consumers or third-party payors.

This, also, is not relevant to any claim currently pending against the Pharmacy Defendants. First, no third-party payor has ever brought a claim against the Pharmacy Defendants. Therefore, as it relates to representations or warranties made to third-party payors, this request is not relevant to any claim or defense in the case. Second, Plaintiffs' Magnuson-Moss Warranty Act claim was dismissed with prejudice, and their breach of express warranty claim against the Pharmacy Defendants was dismissed without prejudice. *See* ECF 775 at 16 (dismissing express warranty claim against the Pharmacy Defendants because the master complaints did not plead an express

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statement made by the Pharmacy Defendants and “the mere act of selling a contaminated product by a downstream entity lacking an obligation to comply with the Orange Book formulation cannot create a bridging argument that translates into an express warranty made by . . . Pharmacies.”). Finally, while Plaintiffs’ implied warranty claim survived dismissal as to a few states, that claim does not seem to be based on any documented statement, but rather is based solely on the fact that the Pharmacy Defendants sold the at-issue products, making this RFP irrelevant to that claim as well. Again, because there is no live claim against the Pharmacy Defendants to which this RFP is relevant, the Pharmacy Defendants should not have to negotiate it at this time.

C. RFP 8

RFP 8 requests “All communications between you and any Wholesaler or Manufacturer Defendants relating to your purchase of, or the recalls of, VCDs.” Ex. A at Request 8. Plaintiffs have remained steadfast that this request demands custodial production.

To be discoverable, information must not only be relevant, but must also be “proportional to the needs of the case” given a series of factors. Fed. R. Civ. P. 26(b)(1). Those factors include “the importance of the issues at stake in the action . . . the parties’ relative access to relevant information . . . the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit.” *Id.* However, given the state of the pleadings, any negotiation regarding proportionality of this request is inefficient and unproductive, and should be tabled pending clarity on the claims asserted against the Pharmacies. This is clear from even a brief consideration of the proportionality factors as they apply to this Request. For example:

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- Importance to the issues at stake in the action. Communications between the Manufacturer/Wholesaler Defendants and Pharmacy Defendants regarding the Pharmacy Defendants' purchases and the recalls (other than the key communications already produced) are not important to the actual issues at stake in the litigation. They have very little, if anything, to do with the main issues in the case—the impurities in the valsartan containing drugs and whether they caused Plaintiffs any damage.
- Parties' relative access to relevant information. Plaintiffs already have the most important documents from the Pharmacy Defendants' previous productions, and should have emails from the Manufacturer Defendants' previous productions, whereas the Pharmacy Defendants would have to begin searching for them from scratch.
- Importance of the discovery in resolving the issues. As noted above, additional documents to be produced in response to RFP 8 are not important at all to resolving the key issues in the case.
- Whether burden or expense of proposed discovery outweighs its likely benefit. As the parties and the Court are well aware, undertaking a custodial search and production is an expensive and timely endeavor. Here the potential likely benefit is low in comparison to this expense (what is a copy of an email regarding a Pharmacy Defendant's purchase of valsartan going to do to advance any issue in this case?), especially given that Plaintiffs likely already have these emails from the Manufacturer Defendants who already negotiated and conducted custodial discovery.

Given the burden of Plaintiffs' request, and the inefficiency of debating these issues while the nature and extent of the claims pending against the Pharmacies remains unclear, common sense dictates that negotiation of this request—and evaluation of these factors—should be tabled.

Moreover, there simply is no urgent need to force negotiations concerning this data. This request essentially seeks documents related to two topics: (1) the Pharmacy Defendants' purchase of valsartan containing drugs and (2) the recalls of valsartan containing drugs. As to the first topic—purchases—the Pharmacy Defendants have already produced sourcing spreadsheets identifying supplier, quantity, date, NDC, *etc.*, as well as exemplar transactional documents that accompanied the valsartan containing drugs they purchased. ECF 509-1 (Original RFPs 1 and 2).

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As to the second topic—communications regarding the recalls—the Pharmacy Defendants have already produced the recall letters they received from the Wholesaler and Manufacturer Defendants, as well as documents showing how the Pharmacy Defendants implemented the recalls in response to the Original RFPs. ECF 509-1 (Original RFPs 14, 16, 18). Plaintiffs, therefore, already have the primary “core” documents related to sourcing and the recalls. The additional information this RFP seems to seek is secondary, email traffic on the two topics, some of which is duplicative of documents already produced by the Manufacturers.⁴ As the claims against the Pharmacy Defendants are shrinking, their discovery obligations should not be increasing. Negotiating a significant expansion of the scope and volume of discovery sought from the Pharmacies therefore makes little sense, and discussion of this request should be tabled until a more concrete, fulsome discussion of proportionality can be had, based on settled pleadings and a clear articulation of the Plaintiffs’ theories of liability against the Pharmacy Defendants.

IV. CONCLUSION

Additional discovery, if any, against the Pharmacy Defendants is not even scheduled to *begin* until June 1, 2021. ECF 863. Despite this, the Pharmacy Defendants have in good faith offered to negotiate six of Plaintiffs’ nine RFPs before this start date while the pleadings and claims against them are not settled. Plaintiffs have refused to compromise *at all*, and their demand that the Pharmacy Defendants must *now* negotiate discovery requests that are not relevant to any existing claim against the Pharmacy Defendants and/or whose burden and expense massively

⁴ The Manufacturer Defendant document requests called for “[a]ll communications between or among any of the defendants” regarding a host of issues, including distribution and sale, and “all communications (and drafts) to or from [any] Defendant regarding recall of valsartan[.]” ECF 328, Ex. A (Manufacturer Document Requests at RFP 10 and 76).

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outweigh any potential benefit given their lack of importance to the central issues in the case and that Plaintiffs already have in their possession the key documents responsive thereto anyway should be rejected.

Sincerely,

A handwritten signature in blue ink, appearing to read "S. Johnston", with a large, stylized loop at the end.

Sarah E. Johnston